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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,078

08/22/2005

Whye-Kei Lye

6614

7590

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Whye-Kei Lye  
1060 Ramblewood Place  
Charlottesville, VA 22901

EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

07/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,078	<b>Applicant(s)</b> LYE ET AL.	
	<b>Examiner</b> SUZETTE J. GHERBI	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64-70 and 79-86 is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 21, 28-30, 34-40, 42-55, 57-59, 61-63 and 71-78 is/are rejected.
- 7) ☒ Claim(s) 19, 22-27, 31-33, 41, 56 and 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/19/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 50 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 50 claims the vessel wall and the intimal, medial and adventitial layers, and is therefore positively claiming a living tissue. The living matter of the present invention is not the result of human intervention; it is of nature, which has been held not patentable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 9-15, 35-38, 47-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Gamble 7,204,847. Gambale discloses the invention as currently claimed noting figures 4-7 comprising:

(**Claim 1, 35**) an expandable body (62, 68) having a proximal end, a distal end, a longitudinal axis there between, and at least one microstructure (64) having an attached end attached to the body and a free end (63) in an un-deployed position along the expandable body; The intended use recitation/functional language “*expansion of the body creating forces which deploy the at least one microstructure from the un-deployed position to a deployed position wherein the free end projects radially outwardly from the expandable body*” carries no patentable weight in the absence of any distinguishing structure. Gambale clearly discloses the structure as claimed and is found to be inherently capable of performing the functions.

Further Gamble discloses (**claim 2**) at least one microstructure has a directional axis between the free end and the attached end, and wherein the directional axis extends along the longitudinal axis while the at least one microstructure is in the undeployed position and wherein the (**claim 3**) at least one microstructure has a directional axis between the free end and the attached end, and wherein the directional axis extends across the longitudinal axis while the at least one microstructure is in the undeployed position. (Claim 4) wherein the free end has a pointed shape (4:38-40).;

(**Claims 7, 9-11, 37-38**) wherein a *material* is carried by the at least one microstructure (the material that is coated is a photo resist material 4:60-67; 5-1-3). As mentioned (regarding **claims 12-14**) supra the functional language of the claims carries

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no patentable weight in the absence of any distinguishing structure. Gambale clearly discloses the structure as claimed and is capable of performing the functions. (**Claim 15**) wherein the body is comprised of stainless steel 4:26-27.

Claims 16-18, 20, 28-30, 36, 40, d under 35 U.S.C. 102(e) as being anticipated by Anderson et al. 5,800,526. Anderson et al. discloses the invention as claimed noting figures 16-17 comprising:

(Claim 16) a radially expandable body (130) having a proximal end, a distal end, a longitudinal axis therebetween, and a plurality of microstructures (140, 142), each microstructure having first and second supports (these are the surrounding struts (14, 15, 17), and a free end, the supports affixed to associate first and second adjacent portions of the radially expandable body, expansion of the expandable body within the patient effecting relative movement between the associated first and second portions of the expandable body, the relative movement deploying the microstructures from an undeployed position along the expandable body to a deployed position with the free end projecting radially outwardly from the expandable body; wherein the at least one microstructure has a directional axis between the free end and the associate first and second adjacent portions, and wherein the directional axis extends along the longitudinal axis while the at least one microstructure is in the undeployed position.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10, 40, 42- 44-46, 55, 57, 58-59, 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale in view of Reed et al. 6,197,013. Gambale has been disclosed supra however does not disclose a gene or drug incorporated in the coating material.

Reed teaches a scaffolding such as a stent (element 1, 6:30-37) with microstructures/probes 5 which carry DNA, drugs, nitric oxide synthase (5:16-40) and the functions of using a balloon force to push the microstructure/probes through the plaque and into the arterial wall to transfer the drugs or DNA. 6:45-49.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the structure of Gambale and incorporate a coating within deliverable substances onto the microstructures/probes as taught by Reed because Gambale teaches that the microstructures could have pointed tips which would facilitate the penetration and delivery of such coating to the surrounding areas, further Reed et al. states that the stent can be made of metal or other materials and stainless steel is a metal capable of being coated with drug delivery.

***Allowable Subject Matter***

Claims 19, 22-27, 31-33, 41, 56 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 64-70, 79-86 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suzette J Gherbi/  
Primary Examiner, Art Unit 3738  
25 June 2008